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| APPLICATION NO.              | FILING DATE                               | FIRST NAMED INVENTOR   | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|------------------------------|---|------------------------|-------------------------|------------------|
| 09/595,167                   | 06/15/2000                                | James M. Brugger       | 17742-002510            | 2793             |
| 7                            | 590 12/16/2002                            |                        |                         |                  |
| James M. Heslin, Esq.        |   |                        | EXAMINER                |                  |
| Two Embarcad                 | and TOWNSEND and CF ero Center, 8th Floor | RODRIGUEZ, CRIS LOIREN |                         |                  |
| San Francisco, CA 94111-3834 |   |                        | ART UNIT                | PAPER NUMBER     |
|                              |   |                        | 3763                    |                  |
|                              |   |                        | DATE MAILED: 12/16/2002 |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

| i   |  | Application No.   | Applicant(s)  |  |  |  |
|---|--|---|---|--|--|--|
| ·   |  | 09/595,167  | BRUGGER ET AL.  |  |  |  |
|   | Office Action Summary  | Examiner  | Art Unit  |  |  |  |
|   | 23   | Cris L. Rodriguez   | 3763  |  |  |  |
| Period fo   | The MAILING DATE of this communication app<br>or Reply   | pears on the cover sheet with   | the correspondence address  |  |  |  |
| THE N - Exten after - If the - If NO - Failui - Any re  | ORTENED STATUTORY PERIOD FOR REPL MAILING DATE OF THIS COMMUNICATION. Is signs of time may be available under the provisions of 37 CFR 1.1 SIX (6) MONTHS from the mailing date of this communication. Period for reply specified above is less than thirty (30) days, a reply period for reply is specified above, the maximum statutory period re to reply within the set or extended period for reply will, by statute epty received by the Office later than three months after the mailing digital patent term adjustment. See 37 CFR 1.704(b). | 136(a). In no event, however, may a reply<br>by within the statutory minimum of thirty (3<br>will apply and will expire SIX (6) MONTH:<br>c, cause the application to become ABAN | be timely filed  0) days will be considered timely.  5 from the mailing date of this communication.  DONED (35 U.S.C. § 133). |  |  |  |
| 1)⊠   | Responsive to communication(s) filed on 23   | September 2002  |   |  |  |  |
| 2a)⊠  | This action is FINAL. 2b) Th   | nis action is non-final.  |   |  |  |  |
| 3)□<br>Dispositi  | Since this application is in condition for allow closed in accordance with the practice under on of Claims   |   |   |  |  |  |
| 4)⊠   | Claim(s) 1-8,10-14 and 16-27 is/are pending  | in the application.   |   |  |  |  |
|   | 4a) Of the above claim(s) <u>4,8,11 and 13</u> is/are  | withdrawn from consideration  | 1.  |  |  |  |
| 5)  | Claim(s) is/are allowed.   |   |   |  |  |  |
| 6)⊠   | ⊠ Claim(s) <u>1-3,5-7,10,12,14 and 16-27</u> is/are rejected.  |   |   |  |  |  |
| 7)  | 7) Claim(s) is/are objected to.  |   |   |  |  |  |
| 8)[   | 8) Claim(s) are subject to restriction and/or election requirement.  |   |   |  |  |  |
| Application   | on Papers  |   |   |  |  |  |
| 9) 🗌 🗆  | Γhe specification is objected to by the Examine  | er.   |   |  |  |  |
| 10) The drawing(s) filed on is/are: a) □ accepted or b) □ objected to by the Examiner.                  |  |   |   |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). |  |   |   |  |  |  |
| 11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.            |  |   |   |  |  |  |
| _   | If approved, corrected drawings are required in re   | •   |   |  |  |  |
| 12) 🗌 🏻   | The oath or declaration is objected to by the Ex   | caminer.  |   |  |  |  |
| Priority u  | nder 35 U.S.C. §§ 119 and 120  |   |   |  |  |  |
| 13)   | Acknowledgment is made of a claim for foreign  | n priority under 35 U.S.C. § 1  | 19(a)-(d) or (f).   |  |  |  |
| a)[   | All b) Some * c) None of:  |   |   |  |  |  |
|   | 1. Certified copies of the priority document   | s have been received.   |   |  |  |  |
|   | 2. Certified copies of the priority document   | s have been received in Appl  | lication No   |  |  |  |
|   | 3. Copies of the certified copies of the prio application from the International Bu ee the attached detailed Office action for a list  | reau (PCT Rule 17.2(a)).  | _   |  |  |  |
| 14)∐ A  | cknowledgment is made of a claim for domesti   | ic priority under 35 U.S.C. § 1   | 19(e) (to a provisional application).   |  |  |  |
|   | The translation of the foreign language process  | * *   |   |  |  |  |
| Attachment  | (s)  |   |   |  |  |  |
| 2) Notice   | e of References Cited (PTO-892)<br>e of Draftsperson's Patent Drawing Review (PTO-948)<br>nation Disclosure Statement(s) (PTO-1449) Paper No(s) _  | 5) Notice of Info   | nmary (PTO-413) Paper No(s) rmal Patent Application (PTO-152)   |  |  |  |
| J.S. Patent and Tra<br>PTO-326 (Rev   |  | ction Summary   | Part of Paper No. 9   |  |  |  |

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#### **DETAILED ACTION**

### Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 5, 7, 10, 12, 14, 16-21, 23, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Schulte et al (US 4,681,560).

Schulte discloses an implantable port (figs. 1 and 7) and a substance delivering method subcutaneously. The port 28 has a body with a flow passage having an upstream and downstream end, a pressure-responsive valve at 60 positioned in the flow passage downstream portion.

## Claim Rejections - 35 USC § 103

- 3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 4. Claims 6 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulte et al in view of Prosl et al (US 4,569,675).

Schulte discloses the invention substantially as claimed. However, Schulte fails to disclose the housing being made of stainless steel, and the access tube being a blunt cannula.

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Prosl teaches an implantable port where the access tube has a blunt cannula. Given the teachings, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use Prosl's cannula in Schulte's implantable port. Doing so would have delivered a substance to a target site. Also, the selection of a known material based on its suitability (such as the stainless steel for the housing) has been considered as an obvious design choice, as supported by the obviousness determination in *Sinclair* & *Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945).

5. Claims 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulte et al in view of Kaplan et al (US 6,162,238).

Schulte discloses the invention substantially as claimed. However, Schulte fails to disclose the kit having instructions having the steps as claimed, and a package to contain the implantable port and the instructions.

Kaplan teaches a kit (fig. 9) including an implantable system 12,16, instructions, and a package 304 to contain the implantable port and the instructions. Given the teachings, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Schulte's kit by including instructions and a package as evidenced by Kaplan as old and well known. Also, the instructions (descriptive material) are not functionally related to the instruments or tools of the kit (which are not even a substrate for the printed matter), and, as such, do not distinguish the invention from the prior art. *In re Gulack*, (CAFC) 217 USPQ 401; *In re Miller*, (CCPA) 164 USPQ 46.

### Response to Arguments

6. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

In response to applicant's arguments to Kaplan, the examiner disagrees. The current application receives the benefit of the earliest effective filing date for the implantable port and its method as January 18, 1994, and the effective filing date of the current application, June 15, 2000, for the kit and instructions.

### Conclusion

- 7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Newkirk, and Dormandy, Jr. et al.
- 8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cris L. Rodriguez whose telephone number is (703) 308-2194. The examiner can normally be reached on 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

December 3, 2002

Cris L. Rodriguez Examiner Art Unit 3763

BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700